-20-07

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. : 10/525.986

Applicants : Tadashi NAKAJIMA et al.

Filed

: February 25, 2005

: THERAPEUTIC AGENT FOR GLAUCOMA COMPRISING Rho KINASE INHIBITOR AND

PROSTAGLANDIN

: 1618

Examiner

: Zohreh FAY

Docket No.

: 05116/HG

Confirm No.: 5004

Customer No.: 01933

Express Mail Mailing Label No.: EM 155 716 583 US Date of Deposit: August 16, 2007 I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 with sufficient postage on the date indicated above and is addressed to: MAIL STOP AMENDMENT Commissioner for Patents.

Dorothy DeFrancesco

P.O. Box 1450 Alexandria, VA 22313-1450

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by Form PTO-2038 attached hereto, authorization to charge the extension fee, or any other fee required in connection with this Paper to Account No. 06-1378.

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

MAIL STOP AMENDMENT

SIR:

Submitted concomitantly herewith are the following:

- (1) A copy of a Supplementary Partial European Search Report, which issued in the counterpart European application;
- (2) IDS Forms. It is respectfully requested that initialed copies of the enclosed IDS Forms be returned to the undersigned to indicate that the publications listed therein have been considered and made of record; and

 $\hspace{0.1in}$ (3) Copies of the non-U.S. patent documents cited in said IDS Forms.

Each of the cited publications, which are disclosed in the enclosed Search Report, is considered relevant or material to the patentability of the present claims in view of the citation thereof in said Search Report.

Said Search Report is in English, thereby satisfying the requirements for a concise explanation of relevance for the publications cited therein.

The following publication, which was cited in the enclosed Supplementary Partial European Search Report, was cited in the INFORMATION DISCLOSURE STATEMENT dated May 16, 2005:

HONJO MEGUMI et al., "Effects of Rho-associated protein kinase inhibitor Y-27632 on intraocular pressure and outflow facility," <u>Investigative Ophthalmology & Visual Science, Association for Research in Vision</u>, Vol. 42, No. 1, January 2001, pp. 137-144.

The following is a copending related application: Serial No. 10/535,000 (published as US 2006/0052367).

The enclosed IDS Forms include publications cited in application Serial No. 10/535,000.

Respectfully submitted,

RICHARD S. BARTH REG. NO. 28,180

FRISHAUF, HOLTZ, GOODMAN & CHICK, P.C. 220 FIFTH AVENUE, 16th FLOOR NEW YORK, NEW YORK 10001-7708 Tel. Nos. (212) 319-4900

(212) 319-4551/Ext. 219 Fax No. (212) 319-5101

E-Mail Address: BARTH@FHGC-LAW.COM RSB/ddf

- Encs.: (1) copy of Supplementary Partial European Search Report dated June 6, 2007
 - (2) IDS Forms
 - (3) copies of the non-U.S. patent documetns cited on the enclosed IDS Forms

| IDS E | FORM | | 1 | 1 6 2007 | | tion Number | k Office: U.S. DEPARTMENT OF COMMERCE 10/525,986 | | | | | |
|--|-------------------------|-------------|----------------------------|------------------------------|---|--|---|---------------------|----------------|--|--|--|
| | | | AU AU | , , , , , , , , | Filing | Date | February 25, 2005 Tadashi NAKAJIMA | | | | | |
| INFOR | | | SCL | RE MAN | First N | amed Inventor | | | | | | |
| DIAII | 31415141 | D1 1 | rruic | 1111 | Group A | rt Unit | | | | | | |
| | | | | | Examine | r Name | Zohreh FAY | | | | | |
| Sheet | | 1 | of | 3 | Attorne | y Docket Number | 05116/HG | | | | | |
| | | | | ט | .S. PATE | ENT DOCUMENTS | | | | | | |
| Exam. Inits* | Cite No ¹ | Docum | ent Numi | per | Kind Code ² | Name of Patentee of Applicant | Publication Relevan Date MM-DD-YYYY Portion | | | | | |
| /S.B./ | | 2006 | /005236 | 7 | A1 | HATANO et al. | 03-09-2006 | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | , | | | FO. | REIGN PA | ATENT DOCUMENTS | | | | | | |
| Exam Inits | Cite No¹ | Offc3 | Documer | rOl | Kind Code ⁵ | Name of Patentee of Applicant | Publication Date MM-DD-YYYY | Relevant Portion | T | | | |
| Exam Inits' | Cite No ¹ | offc³ WO | Documer 00/257 | nt Number4 | Kind | Name of Patentee of | | | T ⁴ | | | |
| /S.B./ | Cite No ¹ | | | nt Number ⁴ | Kind Code ⁵ | Name of Patentee of Applicant | Date MM-DD-YYYY 05-11-2000 10-05-2000 | | T a | | | |
| /S.B./ /S.B./ | Cite No ¹ | WO | 00/257 | nt Number ⁴ 71 | Kind Code ⁵ | Name of Patentee or Applicant SYNPHORA AB SANTEN PHARMACEUTICAL CO | Date MM-DD-YYYY 05-11-2000 10-05-2000 | | | | | |
| /S.B./ /S.B./ /S.B./ | Cite No ¹ | WO | 00/257 00/579 | nt Number ⁴ 71 14 | Kind Code ⁵ A1 A1 | Name of Patentee or Applicant SYNPHORA AB SANTEN PHARMACEUTICAL CO LTD ALCON LABORATORIE | Date MM-DD-YYYY 05-11-2000 10-05-2000 | | <u> </u> | | | |
| Exam Inits' /S.B./ /S.B./ /S.B./ | Cite No ¹ | wo wo | 00/257 00/579 93/167 | nt Number ⁴ 71 14 | Kind Code ⁵ A1 A1 A2 | Name of Patentee or Applicant SYNPHORA AB SANTEN PHARMACEUTICAL CO LTD ALCON LABORATORIE INC | Date MM-DD-YYYY 05-11-2000 10-05-2000 S 09-02-1993 | | | | | |

EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Date

Considered

DATE: August 16, 2007

Examiner

Unique citation designation number. See kinds of U.S. Patent Documents. Enter Office that issued the document, by the two-proceed the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under VIPOS tendands 75.16 if possible. * Place a check here if English translation is attached.

| Please | type | a plus | sign | (+) | inside | this | box → | + | | | | | | | | |
|--------|------|--------|------|-----|--------|------|-------|------|--------|-----|-----------|---------|------|------------|----|----------|
| | | | | | | | | U.S. | Patent | and | Trademark | Office: | U.S. | DEPARTMENT | OF | COMMERCE |

| TDC BOD | ··· | | | | Application | on Number | 10/525,986 | | | | |
|---|--------------|--|--|------------------------------|---------------------------------------|---|---|----|--|--|--|
| IDS FORM INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | | Filing Date February 25, 2005 | | | | | | |
| | | | | | First Named Inventor Tadashi NAKAJIMA | | | | | | |
| | | | | | Group Art | Unit | 1618 | | | | |
| | | | | | Examiner 1 | Name . | Zohren FAY | | | | |
| Sheet | 2 | of 3 | | | Attorney I | Oocket Number | 05116/HG | | | | |
| | | OTHE | ER D | OCUMENTS | - NON-PAT | TENT LITERATU | IRE DOCUMENTS | | | | |
| Examiner Initials | Cite No.1 | Incl pa | ude na | ame of author volume-issu | (in CAPITAL : | LETTERS), title of publisher, city and | article, title of item, date, | T2 | | | |
| /S.B./ | | ZHOU Y | 'AN et | al., "Nonste | roidal Anti-I | nflammatory Drugs (| Can Lower Amyloidogenic Aβ ₄₂ by er 2003, pp. 1215-1217 | | | | |
| /S.B./ | | and Ou | HONIO et al., 'Effects of Protein Kinase Inhibitor, HA1077, on Intraocular Pressure and Outflow Pacility in Rabbit Syes,' <u>Archives of Ophthalmology</u> , Vol. 115, no. 8, August 2001, pp. 117-1175. | | | | | | | | |
| /S.B./ | | DATABA of WO | DATABASE WPI Week 200060, Derwent Publications ltd., London, GB; AN 2000-628321 of WO 00/57914 (Santen Pharmaceutical Co., Ltd.; Oct. 5, 2002) | | | | | | | | |
| /S.B./ | | CLARK Drugs, | CLARK A.F. et al., "Advances in Glaucoma Therapeutics," <u>Expert Opinion of Emerging Drugs</u> , 2002, United Kingdom, Vol. 7, no. 1, May 2002, pp. 141-163 | | | | | | | | |
| /S.B./ | | | UEHATA M. et al., "Calcium Sensitization of Smooth Muscle Mediated by a Rho-Associated Protein Kinase in Hypertension," <u>Nature</u> , Vol. 389, October 1997, pp. 990-994 | | | | | | | | |
| | | Mariko ASAHI et al., "Ryokunaisho to Ryokunaisho Chiryo Yakuzai (Fukuyaki Shido Manual II, Dai 10 Kai)," The Pharmaceuticals Monthly, (1996), 38(9), pp. 2311 to 2331 | | | | | | | | | |
| | | Kunite | ru SH | IRATO, "I. Ry | okunaisho no | Yakubutsu Ryoho 1. | Gairon" (Chiryoyaku no Sentaku | | | | |
| *************************************** | | O Dou Mangaeranoka), ("Some Fractical Aspect in Medical Therapy") Sanka, (2002), 44(11), pp. 1443 to 1448 | | | | | | | | | |
| | | | | | | | Ryokunaisho Chiryoyaku C. Kokan | | | | |
| | | pp. 14 | | | any ana y the part | aronorgro mineagonri | 700 / Galina, (2008), 44(11), | | | | |
| /S.B./ | | Yuichiro OTAKE et al., "Effect and Safety of Combined Therapy with Betaxolol and isopropyl Unoprostone," <u>The Journal of the Eye</u> , (2000), 17(5), pp. 687 to 690 | | | | | | | | | |
| Examiner Signatur | | | | | | Date Considered | | | | | |

^{*} EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DATE: August 16, 2007

¹ Unique citation designation number. 2 Place a check here if English translation is attached.

| Please ty | pe a p | lus sigr | 1 (+) | inside this b | لـــــا | k Office: U.S. DEPARTMENT OF CON | MERC | | | | | |
|--|--------------|---|---|---------------|------------------------|----------------------------------|------|--|--|--|--|--|
| IDS FOR | w | | | | Application Number | 10/525,986 February 25, 2005 | | | | | | |
| | | | | | Filing Date | | | | | | | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | | First Named Inventor | Tadashi NAKAJIMA | | | | | | |
| | | | | | Group Art Unit | 1618 | | | | | | |
| | | | | | Examiner Name | Zohreh FAY | | | | | | |
| Sheet | 3 | | of | 3 | Attorney Docket Number | 05116/HG | | | | | | |
| | | отн | ER D | OCUMENTS | - NON-PATENT LITERATU | RE DOCUMENTS | | | | | | |
| Examiner Initials | Cite No.1 | Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published I | | | | | | | | | | |
| | | Hideki | Hideki TOKUSHIGE, "ROCK Soqaiyaku to Ryokunaisho" ("ROCK Inhibitor and Glaucoma"). BIO | | | | | | | | | |
| /S.B./ | | HOYNG, | Clinica, (2002), 17(13), pp. 1191 to 1194. HOYNG, P.F.J. et al., "Pharmacological Therapy for Glaucoma," <u>Drugs</u> , (2000), 59(3), pp. 411 to 434. | | | | | | | | | |
| /S.B./ | | Combin | Ikuo AZUMA et al., "Effects of Bunazosin Hydrochloride Ophthalmic Solution in Combination with Timolol Maleate Ophthalmic Solution in Patients with Open-Angle Glaucoma and Ocular Hypertension-Comparison with Dipivefrin Hydrochloride Ophthalmic Solution," The Journal of the Eye, (2002), 1992), pp. 261-266 | | | | | | | | | |
| /S.B./ | | Marie A. ABATE et al., "Effect of Naproxen and Sulindac on Blood Pressure Response to Atenolol," <u>DICP - ANNALS. OF PHARMACOTHERAPY</u> , Vol. 24, no. 9, 1990, pp. 810-813 | | | | | | | | | | |
| | = 1 | | | | | | | | | | | |

* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

/Sean Basquill/

DATE: August 16, 2007

Examiner

Signature

Date

Considered

07/16/2008

¹ Unique citation designation number. 2 Place a check here if English translation is attached.